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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
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<i>This Document Relates to:</i>	:	<b>ANSWER AND AFFIRMATIVE</b>
Mary Ruth Burgess	:	<b>DEFENSES OF MERCK</b>
v. Merck & Co., Inc.	:	<b>&amp; CO., INC.;</b>
	:	<b>DEMAND FOR JURY TRIAL</b>
Case No: 1:07-cv-10361-JFK	:	
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Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations directed against it set forth in the Complaint except to the extent such allegations are specifically admitted below:

**I. PARTIES**

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 1.

2. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in Whitehouse Station, New Jersey.

Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 2.

3. Merck admits that it is registered to do business in the State of Alabama, but is without knowledge as to what is meant by the phrase “regularly transacted,” so the remaining allegations in Paragraph 3 are denied.

4. Merck denies each and every allegation of Paragraph 4, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 4 inconsistent with that prescribing information and respectfully refers the Court to the Physicians’ Desk Reference (“PDR”) for FOSAMAX® for its actual language and full text.

5. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 5 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 5.

6. Merck is without knowledge as to what is meant by the phrase “substantial revenue,” so the allegations in Paragraph 6 are denied.

7. Merck is without knowledge as to what is meant by “consequences,” so the allegations in Paragraph 7 are denied.

8. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies the remaining allegations of Paragraph 8.

9. Merck denies each and every allegation of Paragraph 9, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine

FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 9 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

10. Merck denies each and every allegation of Paragraph 10.

11. Merck denies each and every allegation of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12.

13. Merck denies each and every allegation of Paragraph 13.

## **II. JURISDICTION AND VENUE**

14. The allegations of Paragraph 14 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 14.

15. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 15.

16. Merck admits the allegations of the first sentence of Paragraph 16. Merck is without knowledge as to the allegations of the second sentence of Paragraph 16, but for jurisdictional purposes only, admits that the Plaintiff seeks in excess of \$75,000.

17. The allegations of Paragraph 17 are conclusions of law to which no response is required. To the extent that a response is required, Merck respectfully refers the Court to the relevant Case Management Order for its actual language and full text.

### **III. FACTUAL BACKGROUND**

18. Merck denies each and every allegation of Paragraph 18, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

19. Merck denies each and every allegation of Paragraph 19, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 19 inconsistent with that prescribing information and respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

20. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 20 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 20 with respect to Aredia and Zometa inconsistent with that prescribing information.

21. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel,

Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 21 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

34. Merck denies each and every allegation of Paragraph 34, except that Merck admits that Fosamax product sales in 2006 amounted to approximately \$3.13 billion.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

39. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 39.

40. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

#### **IV. COUNTS**

##### **COUNT I: NEGLIGENCE**

47. Merck repleads its answers to Paragraphs 1 through and including 46, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

48. The allegations in Paragraph 48 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

49. Merck denies each and every allegation of Paragraph 49, including each and every allegation contained in subparts (a) through (f).

50. Merck denies each and every allegation of Paragraph 50.

51. Merck denies each and every allegation of Paragraph 51.

**COUNT II: STRICT LIABILITY**

52. Merck repleads its answers to Paragraphs 1 through and including 51, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

53. Merck denies each and every allegation of Paragraph 53, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

54. Merck denies each and every allegation of Paragraph 54, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

55. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

**COUNT III: BREACH OF EXPRESS WARRANTY**

64. Merck repleads its answers to Paragraphs 1 through and including 63, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

65. Merck denies each and every allegation of Paragraph 65, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 68.

69. Merck denies each and every allegation of Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70.

**COUNT IV: BREACH OF IMPLIED WARRANTY**

71. Merck repleads its answers to Paragraphs 1 through and including 70, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.



72. Merck denies each and every allegation of Paragraph 72, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

73. Merck denies each and every allegation of Paragraph 73, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

74. Merck denies each and every allegation of Paragraph 74.

75. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 75.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 77.

78. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

80. Merck denies each and every allegation of Paragraph 80.

**COUNT V: FRAUDULENT MISREPRESENTATION**

81. Merck repleads its answers to Paragraphs 1 through and including 80, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

82. Merck denies each and every allegation of Paragraph 82, including each and every allegation contained in subparts (a) and (b).

83. Merck denies each and every allegation of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

**COUNT VI: FRAUDULENT CONCEALMENT**

90. Merck repleads its answers to Paragraphs 1 through and including 89, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

91. Merck denies each and every allegation of Paragraph 91, including each and every allegation contained in subparts (a) and (b).

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

**COUNT VII: PUNITIVE DAMAGES**

98. Merck repleads its answers to Paragraphs 1 through and including 97, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100, except that it admits that Merck scientists participated in the VIGOR study involving Vioxx®, published in the New England Journal of Medicine, and respectfully refers the Court to the referenced study for its actual conclusions and full text.

101. Merck denies each and every allegation of Paragraph 101, except that it admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

102. Merck denies each and every allegation of Paragraph 102.

103. Merck denies each and every allegation of Paragraph 103, except that it admits that on August 26, 2004, Merck issued a press release regarding the conclusions of a study presented at the 20<sup>th</sup> International Conference on Pharmacoepidemiology & Therapeutic Risk Management and respectfully refers the Court to that press release for its actual language and full text.

104. Merck denies each and every allegation of Paragraph 104, except that it admits that the referenced study exists and respectfully refers the Court to said study for its actual language and full text. Merck further admits that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after

18 months of treatment in the patients taking Vioxx compared with those taking placebo, and that, given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx best served the interests of patients.

105. Merck denies each and every allegation of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

#### **COUNT VIII: PRAYER FOR RELIEF**

107. WHEREFORE, Merck denies that Plaintiff is entitled to any of the relief requested in the Prayer for Relief, and Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

#### **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

#### **FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations, doctrine of prescription, and/or is otherwise untimely.

**SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

**THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

**EIGHTH AFFIRMATIVE DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions,

subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.



**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute

protected commercial speech under the applicable provisions of the United States, Alabama, and New York Constitutions.

**THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff has not suffered any actual injury or damages.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under the doctrine of economic loss.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**FORTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims of fraud are not pleaded with the required particularity.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

The substantive law of Alabama applies to Plaintiff's claims.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

Merck affirmatively pleads that any punitive damages that the Plaintiff may recover in this case should be capped in keeping with Alabama Code Section 6-11-21, as amended in 1999 (Act. No. 99-358) and in the spirit of the Alabama Supreme Court's decision in *Oliver v. Towns*, 738 So. 2d 798 (Ala. 1999).

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

The demand for punitive damages in the instant case is subject to the limitations established by the Alabama legislature and set forth in Ala. Code § 6-11-21 (1975).

Merck adopts by reference the defenses, criteria, limitations, and standards mandated by this Alabama statute. The Alabama Supreme Court's action in abolishing the legislatively created cap on punitive damages was unconstitutional and is without effect. Under the Constitutions of the United States and the State of Alabama, the Alabama Supreme Court cannot abolish the cap created by the legislature on punitive damages through this judicial decision. *See Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415, 114 S. Ct. 2331, 2340 n.9 (1994).

#### **FORTY-EIGHTH AFFIRMATIVE DEFENSE**

Merck avers that the punitive damage cap set out in Ala. Code § 6-11-21 (1975) applies to the instant case. *See Horton Homes, Inc. v. Brooks*, 832 So. 2d 44 (Ala. 2001).

#### **FORTY-NINTH AFFIRMATIVE DEFENSE**

Merck avers that the method of imposing punitive damages violates Amendment 328, Section 6.11 of the Constitution of Alabama, which prohibits the use of a procedural rule to abridge, enlarge, or modify the substantive right of any party. *See Leonard v. Terminix Int'l Co.*, 854 So. 2d 529 (Ala. 2002).

#### **FIFTIETH AFFIRMATIVE DEFENSE**

The imposition of punitive damages is an act of policy making on the part of the judiciary, in violation of Article III, Section 43 of the Constitution of Alabama.

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Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of

its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees, together with such other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York  
December 26, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: \_\_\_\_\_/s/  
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*Attorneys for Defendant Merck & Co., Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 26<sup>th</sup> day of December, 2007, I caused a copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. to be served via first-class mail, postage prepaid, on the following:

CORY WATSON CROWDER & DEGARIS, P.C.  
Annesley H. DeGaris  
2131 Magnolia Avenue  
Birmingham, AL 35205

The above address has appeared on the prior papers in this action as the office address of the attorneys for Plaintiffs.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on December 26, 2007

/s/  
Sarah A. Binder